



## ATTACHMENT B

### REMARKS

By the present amendment, additional amendments have been made to the claims in an effort to utilize the wording directly from the specification and to make it clearer for the Examiner to understand the presently claimed invention and why it is not disclosed in the prior art references. As set forth below, it remains apparent that the Examiner is confused as to the nature of the present invention, and Applicants wish to straighten out this confusion and further point why the invention as presently claimed is patentable over the prior art references. Moreover, the Applicants will again explain that the invention as claimed is directly disclosed in the specification of the present application, and will try to overcome the Examiner's confusion on this point as well. For reasons as stated below, the invention as presently claimed is sufficient described in the original application and is patentable over the cited references which do not, either singly or in combination, disclose the present invention.

With regard to the present amendment, additional language has been added to Claim 16 to follow as closely as possible the wording of Applicants' specification and avoid the confusion the Examiner seems to be having with regard to the inventive subject matter of the present invention. In one aspect of the amendments, the term "sample receiving portion" has been replaced with the term "sample contacting portion" as this language more closely parrots the original application wherein it was disclosed that there were "sample openings 51 through which the liquid test specimen is able to contact the absorbent or sample portions of the test strips." See page 12, lines 7-9. In addition, the claim now more specifically clarifies that the test card has an opening at the test portion and the sample portion with the underlying regions of the test strip

exposed through said openings. This is specifically disclosed at page 11, lines 18-20 wherein the specification discloses that in the modified test card of Fig. 9, "the test strips are covered but the pertinent test and sample portions of the test strips are exposed through openings." This pattern is also shown in the modified version disclosed as Fig. 11. Additionally, Applicant has replaced the term "fluid sample" in the claims with the term "liquid test specimen" as recited precisely at page 12, lines 7-9 of the specification. Finally, Applicant has amended Claim 16 to add the subject matter of Claim 17 relating to the longitudinal extended slot having a closed end in which the test strip sits. Accordingly, all of these amendments are directly supported in the specification.

For reasons as expressed below, the invention as presently claimed is completely and sufficiently described in the specification so as to readily allow one skilled in the art to practice the invention, and is not disclosed in the prior art either singly or in any combination of references cited by the Examiner.

As stated above, in the most recent Official Action, the Examiner exhibits a lot of confusion with regard to the invention, and thus Applicants will attempt to clear up this confusion on the part of the Examiner. For example, in the passage of the Official Action at the top of page 5, the Examiner makes the following statement:

Applicant urges that the **immunoassay test strips** of the instant invention comprise an improvement to obtain a test more quickly and accurately. This is not found persuasive because there is nothing to support applicant's asserted improvement. **Applicant clearly admits that the test strips for performance of the immunoassay were commercially available** (see pages 8-9).

See Final rejection, Page 5, lines 1-4 (emphasis added). This passage alone reflects that the Examiner clearly does not possess an understanding of the invention, and perhaps explains why the Examiner cannot grasp that the invention is completely and

accurately described in the specification. While the Examiner emphasizes that the invention relates to an improvement with regard to “immunoassay test strips” and goes even further to state that “Applicant clearly admits that the test strips for performance of the immunoassay were commercially available,” he makes it clear that he does not understand that the invention itself is to a test **card** for testing a liquid test specimen for a drug of abuse via an immunoassay, and **not** to “test strips”.

Instead, as shown in the embodiment in Figs. 9-11, and as described in detail above, the invention relates to a test card designed to house conventional immunoassay test strips, and to retain those strips in such a manner so that the liquid test specimen will contact the test strip at the absorbent sample contacting portion on the portion of the test strip exposed by the sample contacting opening, and then move by capillary action up the test strip to the test portion of the strip wherein any analyte in the liquid test specimen can be visually detected through the test opening directly above the test portion of the strip. As the Examiner acknowledged, though failed to appreciate the significance of that acknowledgement, the test strips are **conventional** and are **not** part of the improvement to the test card art provided by the present claims.

Accordingly, the Examiner needs to distance himself from the notion that the present invention and the improvements provided thereby relate **at all** to the test strips themselves, which are conventional, but instead to an **improved test card** with features and advantages not shown or obvious from **any** of the prior art references. It is hoped that this detailed description about the nature of the invention as reflected in the present claims will clarify the situation for the Examiner and eliminate any confusion the Examiner seems to have with regard to the invention as presently claimed. Once this confusion is resolved, it is assumed that the Examiner will appreciate the nature of the

claimed invention and realize that it is completely described in the specification, and completely different than the cited prior art references.

In the Final Rejection, the Examiner maintained a rejection of Claims 16-19 on the basis of the written description requirement, asserting that the specification did not disclose adequately to one skilled in the invention that Applicant had possession of the invention at the time the application was filed. However, in this rejection, the Examiner made reference to irrelevant issues such as whether the conventional test strip as disclosed in the invention had "an absorbent pad at the sample receiving portion" or whether they had a "conventional backing or sandwiching with plastic." Moreover, the Examiner ignored the passages of the specification and the drawing figures which specifically call for a test card having openings which exposed the sample contacting portion and the test portion of the test strip, through which the test strip is contacted by the liquid test specimen when the test process is initialed. See the discussion above and in Applicant's prior papers in this application, pages 11-14, and Figs. 9-11.

Moreover, Applicants have further pointed out that the specification describes the test card in such a manner that the lowermost edge of the test strip is blocked by the lower end of the test card, as shown in Fig. 9, which further emphasizes that the lower test strip end is blocked in the claimed test card, and the liquid test sample has to flow through the sample contacting opening to impinge upon the sample contacting portion of the test strip so as to initiate the testing procedure and start the liquid specimen flowing towards the test portion through capillary action. Finally, the specification clearly points out that the liquid specimen travels through the opening "to contact the absorbent", see page 12, lines 7-9, and thus it is clear that the specimen is contacting the absorbent portion of the test strip when in place in the test card of the invention.

With regard to the test strips of the invention, the Examiner has now acknowledged that they were conventional, and in these conventional strips, there is included an absorbent portion wherein the specimen contacts the strip at a flat surface at the lower end of the strip, and a test portion wherein the fluid of the specimen will flow along the strip via capillary action from the absorbent area to the test area. The conventional strip contains a plastic film backing behind the absorbent material so as to maintain the integrity of the strip but not affect the capillary action in the absorbent part of the strip. As Applicant has repeatedly pointed out, such strips are conventional and are disclosed in numerous references, including US Pat. App. Pub. 2005/0009203. The disclosure of the test strips as conventional was made in Applicant's specification, and specific commercial embodiments of these test strips were recited as well.

Accordingly, Applicant fully and completely described what is a conventional element, and not part of the improvement provided by the claimed test card of Applicant's invention. In this regard, Examiner's statement that with regard to the test strips that "a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement (see Final Rejection, Page 3, lines 15-16, once again merely reflects the confusion that the Examiner has with regard to the invention. In particular, the invention as described in the specification clearly relates to a test card whereby improved and efficient lateral flow immunoassay procedures can be carried out. The fact that the test strips utilized in the test card of the invention are conventional means that they needn't have been disclosed in detail to begin with (see *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81,94 (Fed. Cir. 1986). However, Applicant not only described the test strips in detail, the specific commercial embodiments of the test strip were specifically set forth in the specification, providing

further specific information with regard to the types of strips that would be useful with the present invention.

Accordingly, the Examiner's reference to the description of the test strips at most "rendering obvious a claimed invention" just further reflects the confusion that the Examiner has with regard to the invention which is directed to the test card and not the test strips. Indeed, Applicant's disclosure of the test strips in the present specification goes beyond what would have been required for the complete disclosure of the test card of the present invention in light of the fact that this element was conventional, and in fact further reflects that the invention as presently claimed is precisely disclosed in the specification and satisfies the written description requirement. The Examiner's rejection of the claims under 35 U.S.C. §112 is respectfully traversed and should be withdrawn.

In the Final Rejection, the Examiner rejected Claims 16 and 19 under 35 U.S.C. §103 on the basis of May et al. PCT application WO 88/08534 in view of Sun et al. (US 5,238,652), but this rejection has been made moot by the incorporation of the subject matter of non-rejected Claim 17 into Claim 16.

In addition, the Examiner rejected Claims 16-19 as being unpatentable over May et al. in view of Sun et al., and further in view of Boger et al. US 4,518,565, These rejections, insofar as applied to the claims as amended, are respectfully traversed for the reasons that follow.

As indicated above, it appears that the heart of the Examiner's confusion is that he has focused on the test strips, which are conventional elements and not reflective of the improvements provided by the present invention which is directed to test cards and not test strips. In the Final Rejection, the Examiner's main points for maintaining the

rejection was (1) the reference to the fact that Applicant admitted that test strips were commercially available (see Final Rejection, top of Page 5) and (2) that Applicants' arguments have "attacked the references individually" and thus cannot show unobviousness when the rejections are based on combinations. With regard to the Examiner's reference to the fact that "test strips for performance of the immunoassay were commercially available", as indicated above, such a statement reflects that the Examiner is confused about the invention and has not grasped the fact that the invention relates to the test card having the properties as set forth in Claim 16 and its dependent claims and **not** to a test strip. Accordingly, the Examiner's argument is totally irrelevant to Applicants' claimed test strip and thus cannot constitute a basis for rejection of the claims.

Next, there is the Examiner's oft-used argument that Applicant is "attacking the references individually" when in fact the rejections are based on a combination of references. While this general principle may be appropriate wherein the Examiner has located elements of the claimed invention in two different references and then argues that the combination of the two references makes the invention obvious, it is **not** appropriate in the case where, as here, the Examiner has not shown that the essential elements of the claimed invention are located in **any** reference, much less in a combination of references. For example, an obviousness rejection to a claimed combination of A and B may be appropriate when the Examiner cites reference 1 showing "A" and reference 2 showing "B", and then provides a reason why one skilled in the art would combine the two.

However, **this is not the case with the Examiner's current rejections.** To the contrary, the Examiner is citing the May reference (WO 88/8534), the Sun reference

(US patent 5,238,652) and the Boger reference (US 4,518,565), **none of which disclose the specific test card of the present invention**, namely one wherein the test card houses one or more immunoassay strips wherein the liquid specimen passes through the opening onto the absorbent part of the test strip on its flat side and then proceeds via capillary action along the strip to the test portion wherein an analyte in the specimen may be visually determined. As Applicant has previously pointed out, in no embodiment of May or Sun is there a test card wherein there is a sample opening exposing a sample contacting portion through which the specimen will pass so as to contact the absorbent part of the flat test strip, and instead these references **teach away** from the present invention because they only provide embodiments wherein the lower edge of a test strip is contacted with the fluid sample. Moreover, the Examiner cites the Boger et al. reference for the fact that Boger shows “ridges or other means which facilitate the preferred parallel alignment of the strips”. See Final Rejection at Page 7.

In other words, the Examiner is arguing that May discloses the test card of the presently claimed invention, and the combination of May with the “preferred parallel alignment of strips” from Boger makes the present invention obvious. However, May does **not** disclose Applicant’s claimed invention and in fact teaches away from the invention, and the fact that Boger teaches a “preferred parallel alignment of strips” is **irrelevant** to the patentability of the present claims because it does **not** provide the elements missing from the May reference.

Accordingly, **there is nothing to combine** from the May and Boger references which would together disclose the elements of the present claims directed to a test card, and this the Applicant is not “attacking the references individually where the rejections



are based on a combination of references” as alleged by the Examiner. Instead, Applicant is pointing out that even when May and Boger are combined, it still does not affect the patentability of the present claims because neither May nor Boger disclose the specific features of Applicant's test card, namely a test card whereby a sample contacting opening exposes the sample contacting surface of the test strip beneath said opening so that the initial contact of the test specimen in onto the absorbent part of the test strip, and so that the specimen will quickly travel up the test strip via capillary action wherein the test results can be visually observed at the test portion.

The Examiner's rejections of the claims on the basis of the combination of the May and Boger references, insofar as applied to the claims as amended, are thus respectfully traversed and should be withdrawn.

In light of the amendments and arguments as set forth above, and the attachments hereto, Applicants respectfully submit the present application has been placed in condition for allowance, and such action is earnestly solicited.

**END OF REMARKS**